

WHAT WE CAN LEARN ABOUT RESEARCH ETHICS FROM EXPERIENCED SUBJECTS

Rebecca Dresser, JD

Washington University in St. Louis

NPR Interview: Doctors with Cancer



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YOUR HEALTH

When Physicians Get Cancer

April 6, 2006 · 5:17 PM ET
Heard on Morning Edition

JOANNE SILBERNER

Dealing with a potentially fatal cancer is difficult for anyone, but doctors with cancer face a special challenge. They're accustomed to giving medical care, not receiving it. And they know better than most what their future might look like.

Dr. William Tierney, an internist with Indiana University School of Medicine, wasn't happy being known all of a sudden as "the guy with cancer."

"You want to be normal, not self-pitying or any more dependent than you have to be," says Tierney.

For Dr. Elizabeth McKinley, an internist with Case Western Reserve University School of Medicine, knowledge that she had cancer hit her at odd times, sapping her hope.

"I'd find myself just weeping," she recalls, asking herself, "Will I see my kids get older? Am I going to die? Will I be in pain? Will my husband be all right?"

Tierney learned he had lymphoma at the age of 48.

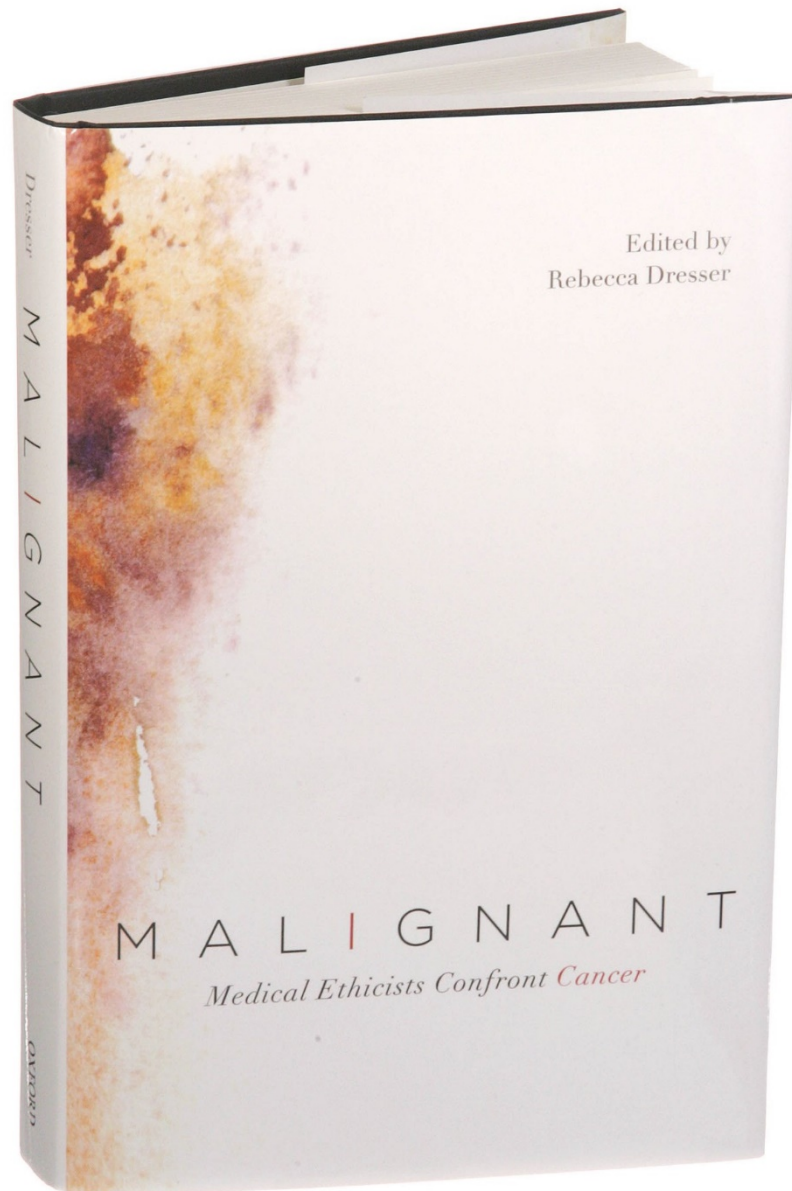


Nine years after her initial treatment, Dr. Elizabeth McKinley's breast cancer returned and has now lodged in her bones.

Case Western Reserve University School of Medicine



Malignant: Medical Ethicists Confront Cancer



Silent Partners: Human Subjects and Research Ethics



Silent Partner Chapters

- **1 Subject Perspectives: The Missing Element in Research Ethics**
- **2 Personal Knowledge and Study Participation**
- **3 The Everyday Ethics of Human Research**
- **4 The Hidden World of Subjects: Rule-Breaking in Clinical Trials**

Silent Partner Chapters

- **5 Participants as Partners in Genetic Research**
- **6 Terminally Ill Patients and the “Right to Try” Experimental Drugs**
- **7 Embedded Ethics in Developing-Country Research**
- **8 Research Subjects as Literary Subjects**
- **9 How to Hear Subjects**

Trial record **1 of 1** for: nct00705068

[Previous Study](#) | [Return to List](#) | [Next Study](#)

Combination Chemotherapy and Radiation in Treating Patients With Stage III or IV Head and Neck Cancer (Paradigm Trial)

This study has been completed.

Sponsor:

Dana-Farber Cancer Institute

Collaborator:

National Cancer Institute (NCI)

Information provided by (Responsible Party):

Robert I. Haddad, MD, Dana-Farber Cancer Institute

ClinicalTrials.gov Identifier:

NCT00095875

First received: November 9, 2004

Last updated: October 25, 2013

Last verified: October 2013

[History of Changes](#)

[Full Text View](#)

[Tabular View](#)

[Study Results](#)

[Disclaimer](#)

[? How to Read a Study Record](#)

► Purpose

RATIONALE: Drugs used in chemotherapy, such as docetaxel, cisplatin, fluorouracil, and carboplatin, work in different ways to stop tumor cells from dividing so they stop growing or die. Radiation therapy uses high-energy x-rays to damage tumor cells. Combining chemotherapy with radiation therapy may kill more tumor cells. It is not yet known which regimen of chemotherapy and radiation therapy is most effective in treating head and neck cancer.

PURPOSE: Randomized phase III trial to compare the effectiveness of two different regimens of chemotherapy and radiation therapy in treating patients who have stage III or stage IV head and neck cancer.

<u>Condition</u>	<u>Intervention</u>	<u>Phase</u>
Head and Neck Cancer	Drug: carboplatin Drug: cisplatin Drug: docetaxel Drug: fluorouracil	Phase 3

Study Type: [Interventional](#)

Study Design: [Allocation: Randomized](#)

[Intervention Model: Parallel Assignment](#)

[Masking: Open Label](#)

[Primary Purpose: Treatment](#)

My Options

- Tumor Board Recommendation: 4 Chemotherapy drugs + radiation
- Trial: Random assignment to receive 3 chemotherapy drugs + radiation OR 1 chemotherapy drug + radiation OR a different chemotherapy drug + radiation

What I Learned (1)

- **Clinical Equipoise = Experts Uncertain about Which Treatment is Best**
- **In Equipoise, Patient-Subject has Reasonable Chance of Receiving the Best Treatment**
- **But Equipoise is Fuzzy in Cancer Trials**

What I Learned (2)

- **Time-Consuming Parts of Study Enrollment = Treatment Delay**
- **Treatment Delay Is Unrecognized Research Burden for Seriously Ill Prospective Subjects**

What I Learned (3)

- **Diagnosis of Serious Illness Increases Dependency on Doctors**
- **Doctors Describing Trials Can Easily Influence Patients on Enrollment Decisions**
- **I was Lucky to Have a Doctor Who Supported My Freedom to Say No to Trial**

What I Learned (4)

- **Some Ethicists and Others Argue that Everyone Has a Duty to Participate in Research**
- **Advocates of Duty Haven't Acknowledged the Burden This Would Impose on Seriously Ill Patients**

Learning from Other Subjects

- **Personal stories of research participation**
- **Empirical Studies of Subjects' Perceptions and Views**
- **Research Subjects in Fiction**

The Subjectivity of Subjects

- **Subjects Are People, Too!**
- **Subjects Are Moral Agents Who Don't Necessarily See Research the Way That Experts Do**
- **Researchers Watch Subjects, but “The Watched Can Watch As Well”**

Deception in Research

- **Deception Goes Two Ways -- Subjects Don't Always Do What Researchers Tell Them To**
- **Some Subjects Successfully Conceal This from Researchers, Reducing the Value of Study Findings**
- **Subject Deception Is a Neglected Ethical Problem**

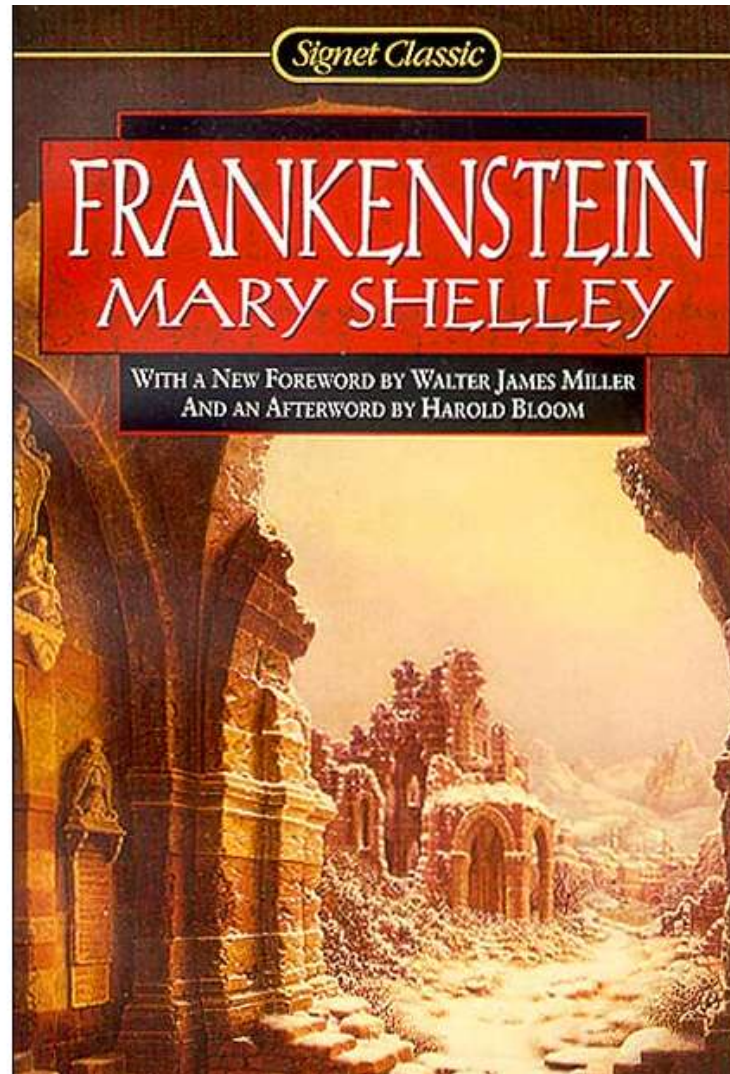
Everyday Research Ethics

- **Subjects Want Courtesy and Professional Behavior From Researchers**
- **Rudeness, Arrogance, and Disorganization Lead to Resentment and Study Drop Outs**
- **Ethical Principle of Respect for Persons as Subjects See It**

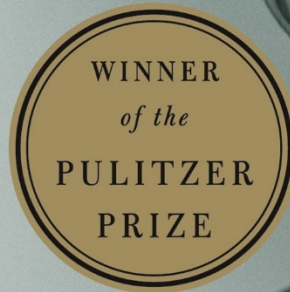
Choosing for Dementia Patients

- **Ethical Guidelines Tell Surrogate Decision Makers To Choose What Patient Would Want If Competent**
- **But Empirical Studies Show Surrogates Focus As Much or More on Patients' Current Best Interests**
- **Surrogates Take Patients' Own Views into Account, Too**
- **Reality Doesn't Match Ethical Guidelines**

A Famous Research Subject



"An original and urgent work of art . . .
Among the finest plays of the decade."
—DONALD LYONS,
THE WALL STREET JOURNAL



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A Play by

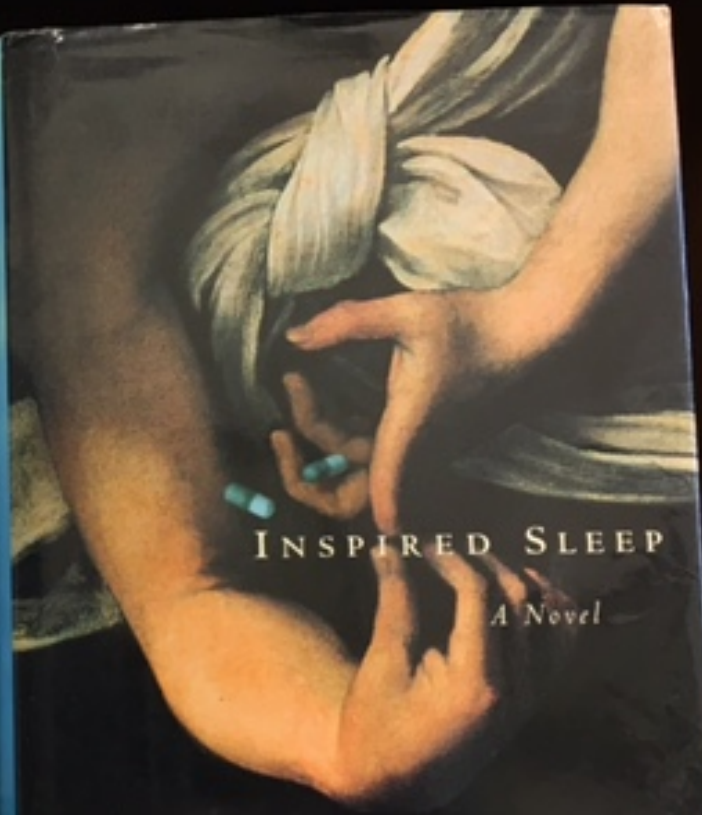
Margaret Edson

the normals

a novel

David Gilbert

author of *Remote Feed*



INSPIRED SLEEP

A Novel

ROBERT COHEN

AUTHOR OF *THE HERE AND NOW*

Richard Beck
Doubt, Faith
From Chance to Choice
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eerie, brilliant and touching"
—The New York Times

WHITE NOISE

NEW YORK TIMES BESTSELLER

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SUPER

SUPER

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HEARTFELT."
—THE NEW YORK
TIMES

SAD

SAD

SAD

"A TOUR DE FORCE."
—BOSTON SUNDAY
GLOBE

TRUE

TRUE

TRUE

A NOVEL

LOVE

LOVE

LOVE

"DEVASTATINGLY
FUNNY."
—LOS ANGELES
TIMES

STORY

STORY

STORY

AUTHOR OF
ABSURDISTAN

GARY SHTEYNGART

Tenth
of ——— *stories* ———
Dec



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SAUNDERS

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Subjects As Real Research Partners

- **Experienced Subjects Belong in IRBs, Research Ethics and Policy Advisory Groups**
- **Experienced Subjects Belong in Patient-Centered Research Activities**
- **Challenges Exist But Are Manageable**
- **For More Egalitarian Model, Consult People Who Know What It's Like to Be Subjects**